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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/596,073 06/16/00 BOLOGNA

W 254/304

022249  
LYON & LYON LLP  
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633 WEST FIFTH STREET  
LOS ANGELES CA 90071-2066

HM22/0228

EXAMINER

PRYOR, A

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

02/28/01

**Please find below and/or attached an Office communication concerning this application r  
proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/596,073

Applicant(s)

BOLOGNA ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5, 7-9, 11-13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 6, 10 and 14 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Duplicate Claim, Warning***

Applicant is advised that should claims 1; 3; and 6 be found allowable, claims 11,15,16; 4,5,12; and 13, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,7-9,11-13,15,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bologna et al (US 5,543,150; 8/6/96).

Bologna discloses a composition comprising progesterone, cross-linked polycarboxylic acid (polycarbophil), and water soluble polymer (Carbopol 934P). Bologna teaches a method of delivering the composition to a mucosal surface (vaginal cavity).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bologna as applied to claims 1,3-5,7-9,11-13,15,16 above in further view of Bologna above. Bologna teaches all that is recited in claim 2 except for the composition/method comprising progesterone in about 50% or less. One having ordinary skill in the art would have been expected to determine the optimum amount of progesterone through routine experimentation. One would have been motivated to do this in order to make a composition and to develop a process that would supply progesterone to the vagina.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-5,7-9,11-13,15,16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,6-8,10,13-16 of U.S. Patent No. 5,543,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition taught by the instant application and delivery system taught by the Patent have the same ingredients.

At this time, **U.S. application no. 09/379,310 or attorney docket no. 525.023/9944 is unavailable** to the examiner. In response to this office action, please provide examiner with a copy of the allowed claims in application no. 09/379,310. Also, if appropriate, provide a terminal disclaimer for application no. 09/379,310 with to the instant application at the time of your reply to this action.

***Claim Objection / Allowable Subject Matter***

Claims 6,10,14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose or suggest the instant composition and method comprising testosterone.

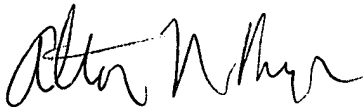
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703 308-4628. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703 305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

A handwritten signature in cursive script, appearing to read "Alan N. Meyer".

ANP  
February 24, 2001